Q-TECH™ PROGRAMMER
A COMPONENT OF THE S-ICD® SYSTEM
USER'S MANUAL

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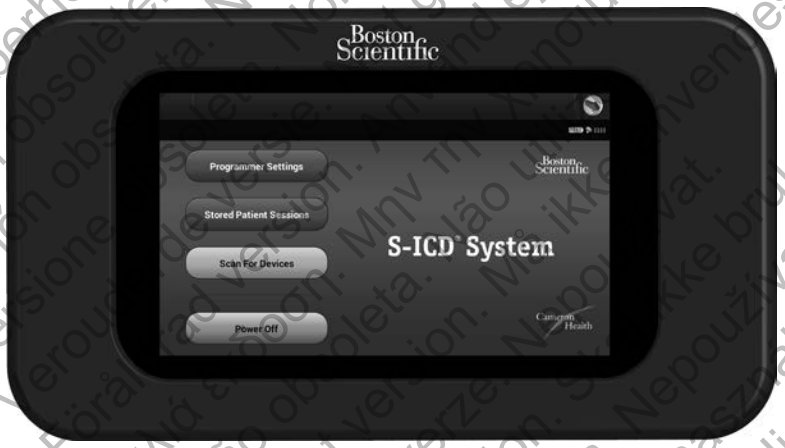

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Description

The Q-TECH Programmer (the "programmer"), Model 3200, is a component of the Cameron Health/ Boston Scientific S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. The other components of the S-ICD System include the SQ-RX Pulse Generator (the "SQ-RX device"), Q-TRAK Subcutaneous Electrode ("electrode") and the Q-GUIDE Subcutaneous Electrode Insertion Tool ("EIT"). The programmer communicates wirelessly with the SQ-RX device to enable adjustment of programmable settings and data collection. The S-ICD System is designed for ease of use and simplicity of patient management. The S-ICD System has a number of automatic functions designed to reduce the amount of time required for implantation, initial programming and patient follow-up.

Indications for Use

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications

Unipolar pacemakers are contraindicated for use with the S-ICD System.

Programmer Warnings and Cautions

General

- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Use the programmer only with the external power supply packaged with the programmer. Using other accessories may cause damage to the programmer.
- The US power cord is for connection to 110 VAC supply mains. All other power cords are for connection to 230 VAC supply mains. Outside North America, use the supplied power cord that exactly matches your AC electrical outlet.
- To avoid risk of electric shock, the programmer must only be connected to a supply mains with protective earth.
- Mains isolation is achieved by disconnecting the AC power cord. Do not position the programmer or the external power supply in a manner that would make it difficult to disconnect that cord.
- Never use a damaged external power supply or a damaged programmer.

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- The programmer is not waterproof or explosion-proof and it cannot be sterilized. Do not use it in the presence of flammable gas mixtures, including anesthetic mixtures containing air, oxygen, or nitrous oxide.
- Confirm that the programmer is in communication with the intended implanted SQ-RX Pulse Generator.
- The programmer is intended for use by healthcare professionals only. The programmer may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the programmer or shielding the location.
- By design, the programmer emits radio frequencies (403.5 MHz and 2.5 GHz). This may interfere with nearby equipment. Closely monitor medical electrical equipment in the vicinity when using the programmer.
- The presence of other equipment in the same frequency band (403.5 MHz for the SQ-RX Pulse Generator and 2.5 GHz for the printer) may interfere with communication. If communication problems occur, refer to the Troubleshooting section of this manual.
- If the programmer is used near other medical or office equipment, all equipment should be observed to verify normal operation. Other equipment may interfere with the programmer, even if that other equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements.
- Use of non-Cameron Health/Boston Scientific-approved accessories may result in increased emissions or decreased functionality of the programmer and may cause unintended operational behavior of the programmer.
- No modification of the programmer is allowed.
- Use only the Cameron Health/Boston Scientific S-ICD programmer and appropriate software to communicate with and program the SQ-RX Pulse Generator.
- Do not discard the programmer in a fire, incinerate, or subject it to temperatures that exceed 100° C (212° F). This could cause the programmer to explode.
- Do not disassemble or alter any parts of the programmer.
- Do not immerse the programmer in liquid of any kind. If the programmer does get wet, contact customer service for information about returning the programmer to Cameron Health/Boston Scientific. Do not attempt to dry the programmer in an oven, microwave, or dryer because this poses a risk of overheating or explosion.

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- Do not subject the programmer to temperatures outside of the -10° C to 55° C (14° F to 131° F) storage range. Exposure to high temperatures may cause the programmer to overheat or ignite, and may possibly reduce its performance and service life.
- Mishandling (such as dropping or crushing) could damage the programmer. If you suspect damage to the programmer, contact your Cameron Health/Boston Scientific representative or the customer service department for instructions and return packaging.
- The display on the programmer is made of glass or acrylic and could break if the programmer is dropped or if it receives significant impact. Do not use if screen is broken or cracked as this could cause injury .
- Contact your Cameron Health/Boston Scientific representative or the customer service department for assistance or a replacement part.

Electrostatic Discharge (ESD)

The programmer may be affected by ESD. If ESD occurs and the programmer's functionality is affected, attempt to reset the programmer or contact your Cameron Health/Boston Scientific representative or the customer service department for instructions.

- Do not touch or connect the telemetry wand to the programmer unless ESD precautionary procedures are used.

S-ICD System Warnings and Cautions

Before using the S-ICD System, read and follow all warnings and cautions provided in this manual. Refer to the SQ-RX Pulse Generator, Q-TRAK Electrode or Q-GUIDE Electrode Insertion Tool User's Manuals for information on implanting and explanting the S-ICD System.

The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique.

General

- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the SQ-RX Pulse Generator's battery longevity.

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- The S-ICD System has not been evaluated for pediatric use.
- The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

Use of Other Medical Therapies/Diagnostic Procedures

- External defibrillation or cardioversion may damage the S-ICD System. Avoid placing the defibrillation paddles directly over the SQ-RX device or electrode.
- Cardio Pulmonary Resuscitation (CPR) may temporarily interfere with sensing and may cause delay of therapy.
- Do not expose a patient with an implanted S-ICD System to diathermy. The interaction of diathermy therapy with an implanted SQ-RX Pulse Generator can damage the SQ-RX Pulse Generator and cause patient injury.
- Do not expose the patient to MRI scanning. MRI scanning can damage the SQ-RX Pulse Generator and cause patient injury.
- Electrical interference or "noise" from sources such as electrosurgical and monitoring equipment can interfere with the communication between the programmer and SQ-RX Pulse Generator or cause inappropriate therapy. If interference occurs, move and reposition the programmer or wand away from the source of the interference.
- Ionizing radiation therapy, such as radioactive cobalt, linear accelerators, and betatrons may adversely affect the S-ICD System operation. Therapeutic ionizing radiation cannot be immediately detected; however, it can damage the electronic components of the SQ-RX Pulse Generator. To minimize the risks of ionizing radiation:
    - » Shield the SQ-RX Pulse Generator with a radiation-resistant material, regardless of the distance between the SQ-RX Pulse Generator and the radiation beam.
    - » Do not project the radiation port directly at the SQ-RX Pulse Generator.
    - » Evaluate the S-ICD System operation after each radiation treatment.
- Lithotripsy and other therapeutic forms of ultrasound can damage the SQ-RX Pulse Generator. If required, avoid direct flow of the pulse waves near the site of the implanted SQ-RX Pulse Generator.
- Use caution during ablation procedures. Program the S-ICD System to Therapy Off. Keep the current path (electrode tip to ground) as far away as possible from the implanted SQ-RX Pulse Generator and electrode.
- The programmer is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

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Electromagnetic Interference (EMI) Outside the Hospital Environment

Exposure to EMI or static magnetic fields may suspend tachycardia detection and possibly cause temporary inhibition of therapy delivery. EMI may also trigger delivery of a shock in the absence of a tachycardia. Automatic sensing and detection of tachycardias will resume when the patient moves away from the EMI or static magnetic field source.

To minimize the risk, advise patients to avoid sources of EMI or static magnetic fields having strengths of >10 gauss or 1 mTesla.

- Sources of EMI include, but are not limited to:
  - » High-voltage power lines
  - » Arc welding equipment
  - » Electrical smelting furnaces
  - » Large radio-frequency transmitters (such as radar)
  - » Alternators on running engines in automobiles
  - » Communications equipment (such as high-power radio transmitters)
- Sources of strong static magnetic fields may include the following:
  - » Industrial transformers and motors
  - » Large stereo speakers
  - » Magnetic wands, such as those used for airport security

Patients should seek medical guidance from their physician before entering an area where a posted sign prohibits patients with an implantable cardioverter defibrillator or pacemaker.

Potential Adverse Events

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following:

- Acceleration/induction of atrial or ventricular arrhythmia
- Adverse reaction to induction testing
- Allergic/adverse reaction to system or medication
- Bleeding
- Conductor fracture
- Cyst formation
- Death
- Delayed therapy delivery

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- Discomfort or prolonged healing of incision
- Electrode deformation and/or breakage
- Electrode insulation failure
- Erosion/extrusion
- Failure to deliver therapy
- Fever
- Hematoma
- Hemothorax
- Improper electrode connection to the pulse generator
- Inability to communicate with the pulse generator
- Inability to defibrillate or pace
- Inappropriate post-shock pacing
- Inappropriate shock delivery
- Infection
- Keloid formation
- Migration or dislodgement
- Muscle stimulation
- Nerve damage
- Pneumothorax
- Post-shock/post-pace discomfort
- Premature battery depletion
- Random component failures
- Stroke
- Subcutaneous emphysema
- Surgical revision or replacement of the system
- Syncope
- Tissue redness, irritation, numbness or necrosis

If any adverse events occur, invasive corrective action and/or S-ICD System modification or removal may be required.

Patients who receive an S-ICD System may also develop psychological disorders that include, but are not limited to, the following:

- Depression
- Fear of shocks
- Phantom shocks

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Setup of the Q-TECH Programmer

Packaging

Programmer components include:

- Model 3200 Programmer with pre-loaded software
- Model 3203 Telemetry Wand
- External power supply and AC power cord

Visually inspect the packaging to ensure the contents are complete. Do not use if there is evidence of damage.

In case of damage return the product to Cameron Health/Boston Scientific. Contact your local representative or the Cameron Health/Boston Scientific customer service department for instructions and return packaging.

Charging the Programmer

The programmer is primarily intended to be operated while connected to the AC-powered external power supply, but may also be operated on battery power provided that the internal battery is adequately charged. The programmer is recharged whenever it is connected to the AC-powered external power supply. When not in use, it is recommended that the programmer remain connected to the external power supply in order to maintain an adequate battery charge.

Typical charge time for a fully discharged battery is 5 hours. However, more time may be required if the programmer is in use while being recharged.

The Battery Status indicator located on the upper right corner of the screen displays the status of the main battery power when the unit is in use:

- All four bars are illuminated (green) - The battery is 100% charged
- Three bars are illuminated (green) - The battery is 75% charged
- Two bars are illuminated (yellow) - The battery is 50% charged
- One bar is illuminated (red) - The battery is 25% charged

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The programmer displays one of the following alert screens as battery power gets progressively lower.

- Programmer Battery Low
- Programmer Battery Critical
- Out Of Power

To charge the programmer:

1. Connect the external power supply cable to the programmer (Figure 1).

Figure 1: *Connecting the external power supply*

2. Plug the external power supply cord into an AC power outlet.

Using the Q-TECH Programmer

Turning the Programmer On

The programmer power button is located in the recess above and behind the left corner of the screen. Press and hold the button until the display screen is active (Figure 2).

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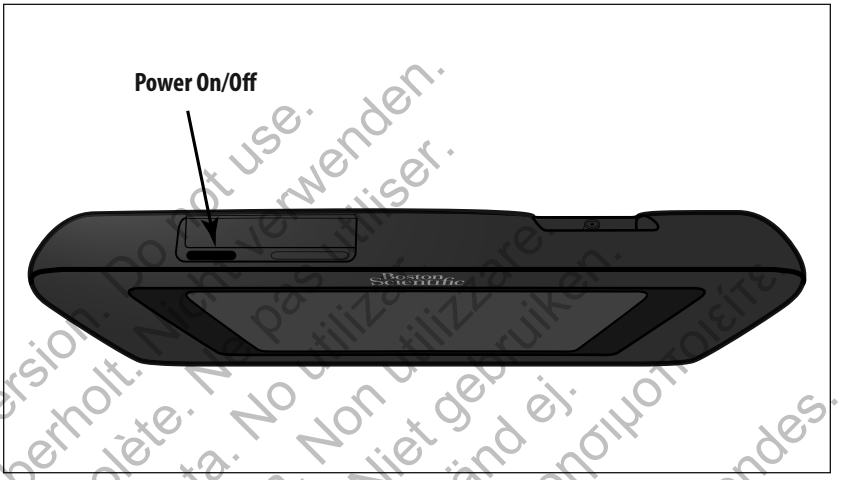

Figure 2: *Turning the programmer On/Off*

Note: *If the programmer cannot be turned on while it is connected to AC power via the external power supply, first unplug the external power supply cord from the programmer. Press and hold the programmer power button until the display screen is active (Figure 2). AC power via the external power supply can then be reconnected.*

Placing the Programmer in Suspend Mode

The programmer has a Suspend Mode which is activated automatically to conserve power. The display will be blank when this mode is in effect.

The programmer enters Suspend Mode whenever:

- The power button (Figure 2) is momentarily pressed and released
- The programmer is not connected to the external power supply, it is not in active communication with an SQ-RX pulse generator, and no user activity has occurred for 15 minutes

Momentarily pressing the power button will resume normal operation.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Version obsolète. Ne pas utiliser.
Versione obsoleta. Non utilizzare.
Versie niet gebruiken.
Använd ej.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μη χρησιμοποιείτε.
Forældet version. Må ikke anvendes.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
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Wersja nieaktualna. Nie używać.

Turning the Programmer Off

There are two ways to turn the programmer off:

1. Press and hold the power button (Figure 2) until the System shutdown menu appears. Select Power off from the popup and confirm by pressing OK.
2. From the on-screen Main Menu, press the Power Off button and select OK at the confirmation prompt.

Using the Programmer Touch Screen

The programmer is equipped with an LCD touch screen. The screen can be adjusted to the desired viewing angle by using the kick-stand located on the back of the programmer. All interaction with the programmer is conducted using the fingers to touch the appropriate areas on the screen. Scroll on-screen lists by sliding a finger up and down the list (Figure 3). An on-screen keyboard is presented whenever text entry is required.

Figure 3: *Scrolling on-screen lists*

Using the Wand

Model 3203 wand ("the wand") makes it possible for this programmer to communicate with the SQ-RX device.

Note: *The wand is a non-sterile device. DO NOT STERILIZE the wand or the programmer. The wand must be contained in a sterile barrier before use in the sterile field.*

Outdated version. Do not use. Version überholt. Nicht verwenden. Version obsolète. Ne pas utiliser. Versión obsoleta. No utilizar. Versione obsoleta. Non utilizzare. Verouderde versie. Niet gebruiken. Föråldrad version. Använd ej. Πολλά παλιά έκδοση. Μην χρησιμοποιείτε. Versão obsoleta. Não utilize. Foreldet versjon. Må ikke anvendes. Zastaralá verze. Nepoužívat. Zastarala različica. Ne uporabljati. Elavult verzió. Ne használja! Wersja nieaktualna. Nie używać.

To connect the wand to the programmer, slide the wand cable connector over the communication connector port located on the rear edge of the programmer (Figure 4).

To disconnect the wand, grasp the wand cable connector and gently pull it straight off the communication connector port.

Note: *Do not pull or yank on the cable to disconnect the wand from the programmer. Such action could cause hidden damage to the cable. A damaged cable might reduce wireless communication capabilities and require a replacement wand.*

Figure 4: *Connecting the wand*

To obtain optimal telemetry, the wand should be placed directly over the implanted SQ-RX device. Although the programmer may receive S-ECG telemetry at greater distances, programming should be performed with the wand placed over the SQ-RX device.

When telemetry loss occurs, the display screen will turn yellow and a message will appear with the text "Communication Loss" to alert the user. Reposition the wand to establish communication. The programmer will display a screen informing the user if the SQ-RX device is found and programming can continue.

Note: *If communication cannot be reestablished, the session should be ended and restarted by scanning for the SQ-RX device.*

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
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Navigation

The programmer's graphic user interface (GUI) facilitates management and control of the S-ICD System. The Navigation Bar and on-screen icons at the top of the screen allow the user to navigate programming software screens. In addition, a continuous subcutaneous electrocardiogram (S-ECG) is displayed along the bottom of the screen during Online (active) communication with the SQ-RX device.

Screen Header

When the programmer is Offline (inactive communication), the screen header displays the Battery Status Indicator.

When viewing Offline Stored Sessions, the screen header displays:

- Patient name
- Therapy On/Off
- Battery status indicator

When the programmer is online (active communication), the screen header displays:

- Therapy On/Off
- Patient name
- Patient heart rate
- Programmer Battery and Telemetry status indicator
- Screen title
- Rescue shock icon

Navigation Bar

The Navigation Bar is the primary method for navigating the Online programmer screens. The bar is located along the top edge of the programmer screen and chosen screens appear with their selection icon highlighted.

Table 1 displays a list of the programmer icons and their corresponding descriptions.

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Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
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Table 1: *Icon descriptions*

Icon	Description	User Application
	Main Menu Button	Allows user to return to the main menu.
	Auto Setup Button	Allows user to access the auto setup menu.
	Device Settings Button	Allows user to access the SQ-RX device settings screen.
	Device Status Button (open folder and closed folder)	Allows user to access the SQ-RX device status screen. User can view number of shocks delivered since the last update as well as the SQ-RX device battery life.
	Patient View Button	Allows user to access the patient chart screen.
	Captured and Stored Episodes S-ECG Button	Allows user to access captured S-ECG and stored episode screens.
	Induction Test Button	Allows user to access induction screen.
	Manual Shock Button	Allows user to access the manual shock screen.
	Battery & Telemetry Meter	Left side of the meter allows user to view the programmer's battery status. The right side of the meter allows viewing of telemetry signal.
	Capture S-ECG	Allows user to capture a live S-ECG.
	S-ECG Display Settings	Allows user to modify the zoom and sweep speed on the live S-ECG.
	Heart Rate Icon	Allows user to view current heart rate.
	Rescue Button	Allows user to administer a shock from any programmer screen.
	Option Selection Slider Switch	Allows user to select one of two options, e.g. A or B

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
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Zastaraná verzia. Nepoužívať.
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Restarting the Programmer

The programmer's operating system is self-monitoring and is generally able to sense many system error conditions and automatically initiate a restart sequence in response. Follow the on-screen instructions to complete the programmer-initiated restart sequence.

The programmer may need to be manually restarted if:

- You cannot exit a screen
- The operating system stops responding

A manual restart is accomplished by pressing and holding the power button until the system shutdown menu appears on the screen. Select Restart from the popup and confirm by pressing OK.

If the programmer does not respond to a restart process, contact your Cameron Health/Boston Scientific/Boston Scientific representative or the customer service department for assistance.

Outdated version. Do not use.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
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Configuring the Q-TECH Programmer

Configuring Programmer Settings

The programmer should be configured before communication with an SQ-RX device is attempted. This includes setting the date and time format, time zone, language and printer. Once these settings are configured during the initial setup process they become the default parameters and will not normally need to be changed with each session.

To configure the programmer settings:

1. Select the Programmer Settings button on the Startup screen (Figure 5) to display the Programmer Settings screen (Figure 6).

Figure 5: *Startup screen*

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
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Versão obsoleta. Não utilizar.
Forældet version. Må ikke anvendes.
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Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
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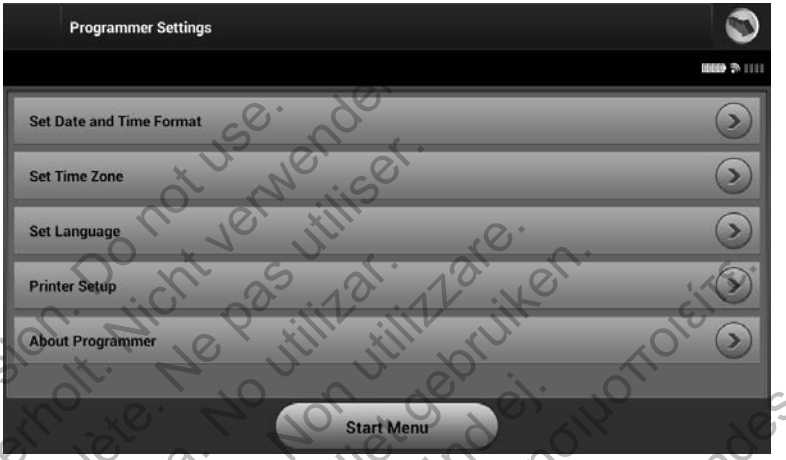

Figure 6: *Programmer Settings screen*

2. Select the corresponding line to access each setting. The settings that can be configured include:
   - Date and time format
   - Time zone
   - Language
   - Printer

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
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Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Date and Time Format

To set the date and time format:

1. Select Set Date and Time Format on the Programmer Settings screen (Figure 6). The Date and Time Settings screen appears (Figure 7).
2. Select the desired date format.
3. Select the Save button to save the changes and return to the Programmer Settings screen, or select Cancel to return to the Programmer Settings screen without saving the changes.

Figure 7: *Date and Time Settings screen*

Time Zone

To set the time zone in which the programmer will be used:

1. Select Set Time Zone on the Programmer Settings screen. The time zone selection screen appears (Figure 8).
2. Select the country/time zone button for the zone in which the programmer will be used. A checkmark will appear in the selected button. The SQ-RX device line frequency of 50 Hz or 60 Hz is automatically programmed based on the country/time zone selected.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
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Set Time Zone
(-10:00) Hawaiian Standard Time
(-9:00) Alaskan Standard Time
(-8:00) Pacific Standard Time: US & Canada
(-8:00) Yukon Standard Time: Canada
(-7:00) Mountain Standard Time: US & Canada
(-6:00) Central Standard Time: US & Canada
Save
Cancel

Figure 8: *Time Zone selection screen (scrollable list)*

3. Select the Save button to save the changes and return to the Programmer Settings screen, or select Cancel to return to the Programmer Settings screen without saving the changes.

Language Preference

To set the language preference:

1. Select Set Language on the Programmer Settings screen. The Language Settings screen appears.
2. Select the Save button to save the changes or select Cancel to return to the Programmer Settings screen without saving the changes. If the language is changed the programmer will automatically restart and return to the Startup screen.

Printer Selection

Only Cameron Health/Boston Scientific-approved printers can be used with the programmer. To select the printer to be used with the programmer:

1. Ensure the printer is on and, as applicable, the wireless function is enabled or the wireless adapter is in the printer's USB port.

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
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Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
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2. Select Printer Setup on the Programmer Settings screen. A previously configured printer becomes the default printer and will be displayed at this time. If a default printer has not already been selected and configured, the programmer will scan the area to locate wireless printers. A Scan Progress Bar will appear informing the user that the programmer is currently scanning for printers.

3. Select the printer of choice (Figure 9). If no printers are found, a window will appear stating that there are no printers. Select the Scan Again button or the Cancel button to return to the Programmer Settings screen. If a printer was selected during another session, the Printer Setup screen is displayed.

Figure 9: *Printer Selection screen*

4. Once the scan is complete, the Printer Selection screen appears (Figure 9).

   Note: *Refer to "Troubleshooting" section for printer problems.*

5. Select the desired printer name and enter the name using the on-screen keyboard (up to 15 characters). A unique printer identifier should appear with the printer selection (Figure 10).

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd inte.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Foreldet versjon. Skal ikke brukes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
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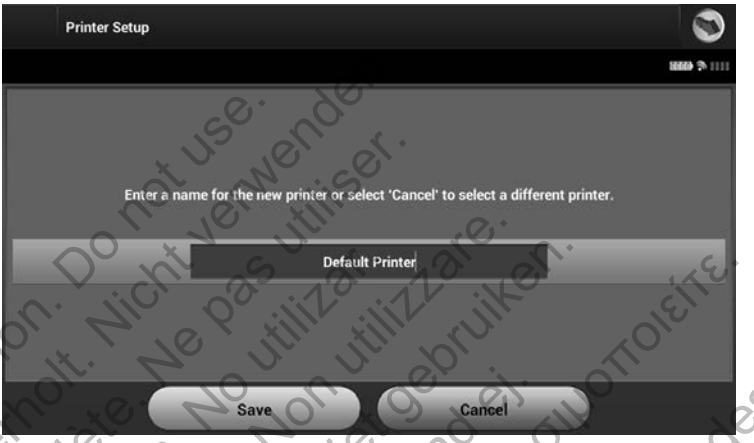
Printer Setup
Enter a name for the new printer or select 'Cancel' to select a different printer.
Default Printer
Save
Cancel

Figure 10: *Use the on-screen keyboard to enter a name for the selected printer*

6. Select the Save button to save the changes and return to the Programmer Settings screen, or select Cancel to return to the Programmer Settings screen without saving the changes. A confirmation screen will appear when the printer setup is completed (Figure 11).

Figure 11: *Printer Setup confirmation screen*

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Version obsolète. Ne pas utiliser.
Versione obsoleta. Non utilizzare.
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Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
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Programmer Software Version

To view the programmer's software version:

1. Select About Programmer on the Programmer Settings screen. The Programmer Software Version information screen appears (Figure 12).

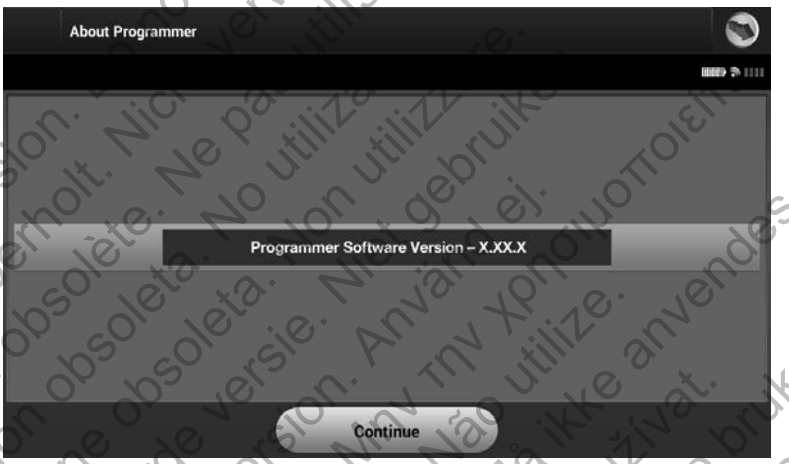

Figure 12: *Programmer Software Version information screen*

2. This screen displays the current version of the programmer software. Select the Continue button to return to the Programmer Settings screen.

Note: *The patient printed report contains the programmer software version.*

Modes of Operation for the Q-TECH Programmer

Online Behavior

The programmer's interface varies according to whether the programmer is Online (actively communicating) or Offline (not communicating) with a selected SQ-RX device.

An Online session begins when the programmer establishes a telemetry link with a specific SQ-RX device. A yellow alert screen is displayed if the telemetry signal is lost between the programmer and the SQ-RX device for more than five seconds during active communication. This may occur if the

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Versione obsoleta. Non utilizzare.
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Föråldrad version. Använd ej.
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Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
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wand is moved out of the telemetry communications range or if noise or interfering objects inhibit communication. Programming commands, including Rescue Shocks, will not be available until telemetry is reestablished.

Telemetry reconnection may occur automatically within one minute when the SQ-RX device and wand are within telemetry range.

Note: *Whenever the programmer is in active communication with an SQ-RX device, charging of the pulse generator in preparation for delivering a shock (whether commanded or in response to a detected arrhythmia) is indicated by an audible notification. The notification continues until the shock is delivered or aborted.*

Offline Behavior

When the programmer is not actively communicating with an SQ-RX device it is Offline. During Offline sessions, programmer settings can be accessed, and stored patient sessions can be viewed and/or printed.

Stored Patient Sessions

During a patient follow-up visit, the programmer will retrieve data from the SQ-RX device's memory. The programmer can store up to 15 patient sessions. When the 16th session occurs, the programmer will automatically replace the oldest stored session with the new data. A stored session includes the following information:

- Captured S-ECG Reports
- Episode History (including any downloaded episodes)
- Patient Data
- Programmed Device Settings

To view stored patient sessions:

1. From the Startup screen, select Stored Patient Sessions.
2. Select the desired patient session.

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Version obsolète. Ne pas utiliser.
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Forældet version. Må ikke anvendes.
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Udatert versjon. Skal ikke brukes.
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Modes of Operation for the SQ-RX Device

The SQ-RX device has three modes of operation:

- Shelf
- Therapy On
- Therapy Off

Shelf Mode

The Shelf mode is a low power consumption state intended for storage only. When communication is initiated between the SQ-RX device and the programmer, a full-energy capacitor reformation is automatically performed and the SQ-RX device is prepared for set-up. Once the SQ-RX device is taken out of Shelf mode, it cannot be reprogrammed back into Shelf mode.

Therapy On Mode

The Therapy On mode is the primary operating mode of the SQ-RX device, allowing automatic detection of, and response to, ventricular tachyarrhythmias.

Note: *The SQ-RX device must be programmed out of Shelf mode before being programmed to Therapy On.*

Therapy Off Mode

The Therapy Off mode disables automatic therapy delivery and enables manual control of shock delivery. Programmable parameters may be viewed and adjusted via the programmer. Also, the subcutaneous electrogram (S-ECG) may be displayed or printed.

The SQ-RX device automatically defaults to Therapy Off mode when the SQ-RX device is taken out of Shelf mode.

Note: *Manual and rescue shock therapy are available once the initial Setup process is complete.*

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Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
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Forældet version. Må ikke anvendes.
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Connecting and Disconnecting from the SQ-RX Device

This section provides the information necessary for selecting, connecting to, and disconnecting from the SQ-RX device.

Scanning For SQ-RX Devices

1. Select the Scan For Devices button on the Startup Screen (Figure 13). The Device List screen appears after the Scan Progress Bar displayed during the scanning process. Select the Cancel button at any time to end the scanning process.

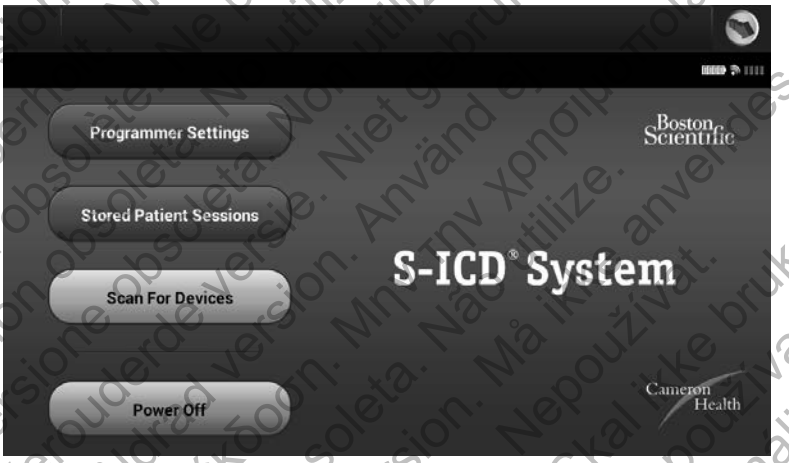

Figure 13: *Startup screen*

Outdated version. Do not use. Version überholt. Nicht verwenden. Version obsolète. Ne pas utiliser. Versión obsoleta. No utilizar. Versione obsoleta. Non utilizzare. Verouderde versie. Niet gebruiken. Föråldrad version. Använd ej. Παλιά έκδοση. Μην χρησιμοποιείτε. Versão obsoleta. Não utilize. Forældet version. Må ikke anvendes. Zastaralá verze. Nepoužívat. Utdatert versjon. Skal ikke brukes. Zastaraná verzia. Nepoužívať. Elavult verzió. Ne használja! Wersja nieaktualna. Nie używać.

2. When the scanning process is complete, a list of all SQ-RX devices detected (up to 16) will be displayed on the Device List (Figure 14). The SQ-RX devices that are in Shelf mode will be displayed as "Not Implanted." Any SQ-RX devices that were previously taken out of Shelf mode are displayed either as "Implanted" or with the stored patient name.

Figure 14: *Device List screen (scrollable list)*

3. If the desired SQ-RX device is not listed, select the Scan Again button to re-initiate the scanning process. Select the Cancel button to return to the Startup screen.

Note: *Refer to the Inability to Communicate with the SQ-RX Device section for further assistance.*

Outdated version. Version überholt. Nicht verwenden. Version obsolète. Ne pas utiliser. Versión obsoleta. No utilizar. Versione obsoleta. Non utilizzare. Verouderde versie. Niet gebruiken. Föråldrad version. Använd ej. Παλιά έκδοση. Μην χρησιμοποιείτε. Versão obsoleta. Não utilize. Forældet version. Må ikke anvendes. Zastaralá verze. Nepoužívat. Utdatert versjon. Skal ikke brukes. Zastaraná verzia. Nepoužívať. Elavult verzió. Ne használja! Wersja nieaktualna. Nie używać.

Connecting to the SQ-RX Device

From the Device List screen, select the desired SQ-RX device to initiate the communication session.

Note: *Regardless of how many SQ-RX devices are located by a scan, the user must select an SQ-RX device from the list to begin active communication.*

Connecting to an SQ-RX Device in Shelf Mode:

1. When the SQ-RX device selection is made, the programmer connects to the selected SQ-RX device. A window will appear indicating connection is in process.
2. Once communication is established with the SQ-RX device, the Device Identification screen appears (Figure 15).

Figure 15: *Device Identification screen*

Note: *The Device Identification screen is visible only while connecting to an SQ-RX device in Shelf mode.*

3. The SQ-RX device model and serial numbers are automatically acquired and displayed during the initial scanning process. Select Continue to remove the SQ-RX device from Shelf mode and prepare for implantation, or select Cancel to return to the Device List screen.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην τη χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Foraldet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Ending a Patient Session

To end an Online patient session and return the programmer to its Offline operation mode:

1. Select the Main Menu button on the Navigation Bar. The Main Menu screen appears.
2. Select the End Session button (Figure 16).

Figure 16: *Main Menu screen*

3. A warning message will be displayed to the user if any of the following conditions exists:
   - Automatic Therapy is programmed to Off
   - Reference S-ECG has not been acquired
   - Automatic Setup or Optimization has not been completed. This message is typically displayed following the implant procedure as Setup Optimization was not performed (Figure 17).
4. Select the Continue button to end the patient session and return to the Startup Menu screen, or select Cancel to remain online and return to the Main Menu screen.

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Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
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Versão obsoleta. Não utilizar.
Forældet version. Må ikke anvendes.
Foreldet versjon. Skal ikke brukes.
Zastaralá verze. Nepoužívat.
Updated version. Nepoužívať.
Zastarana verzija. Ne koristiti.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

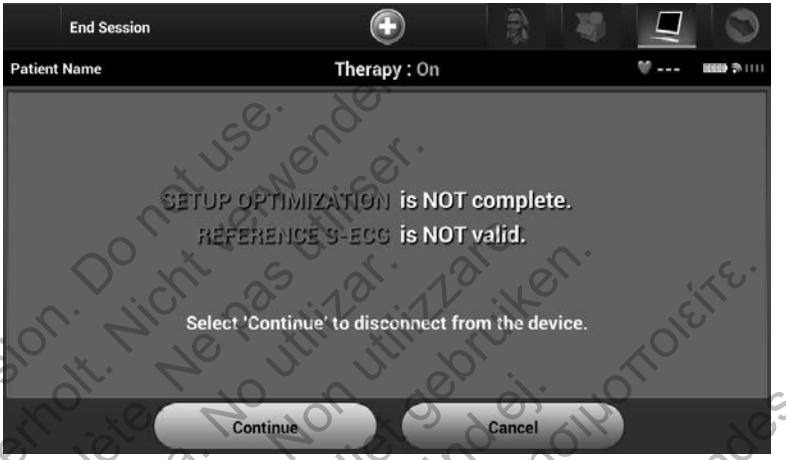

Figure 17: *Session incomplete message*

Note: *Once the Continue button is selected, the session is stored and communication is terminated.*

Note: *In order to confirm that Automatic Therapy is programmed On upon disconnection, always use the End Session process and review all displayed warning messages.*

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Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
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Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
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Zastaraná verzia. Nepoužívať.
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Wersja nieaktualna. Nie używać.

Programming the SQ-RX Device at Implant

This section provides the information necessary for programming the SQ-RX device during an implant setting.

Entering Electrode Information

The programmer maintains information on the implanted electrode. To record this information for a patient's new or replacement electrode:

1. Select the Main Menu button.
2. Select the Implant button.
3. Select the Automatic Setup button in the Navigation Bar.
4. Select Set Electrode ID button (Figure 18).

Figure 18: *Select the Set Electrode ID button to enter electrode information*

Note: *ECG and heart rate information is not present on the Automatic Setup and Electrode ID setup screens until the electrode has been connected to the SQ-RX device.*

5. Enter the electrode model and serial number (Figure 19).

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Version übeholt. Nicht verwenden.
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Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
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Versão obsoleta. Não use.
Foreldet versjon. Må ikke brukes.
Zastaraná verze. Nepoužívat.
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Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

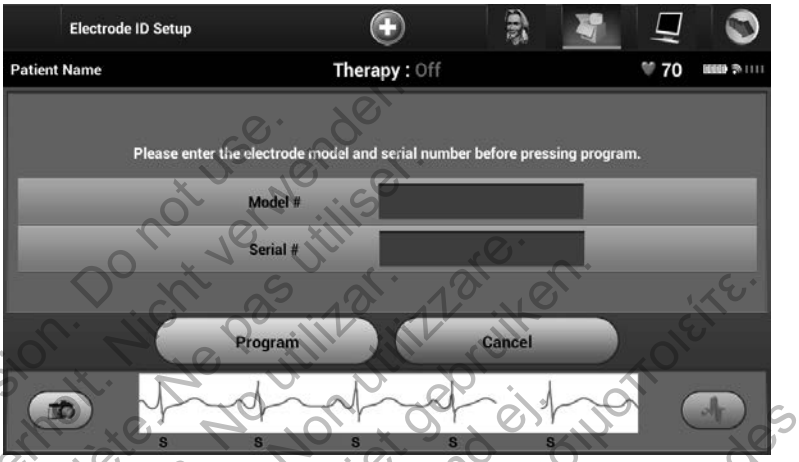

Figure 19: *Entering electrode information*

6. Select the Program button to save the information. A confirmation screen will appear during communication with the SQ-RX device (Figure 20). Select Cancel to cancel information storage and return to the Automatic Setup screen.

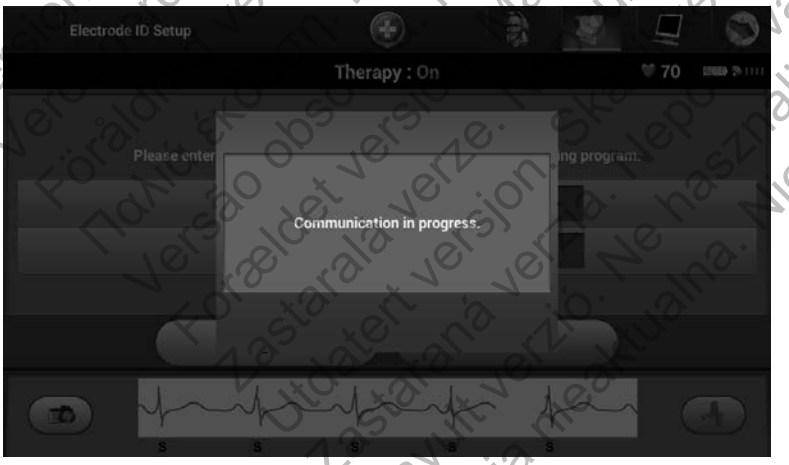

Figure 20: *Confirmation screen showing communication in progress*

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Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Nicht verwenden.
Nonaktuell. Nicht gebrauchen.
Versione obsoleta. Non utilizzare.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μη χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Ikke bruke.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Creating the Patient Chart

This chart contains reference information for the patient. To set up the patient chart:

1. Select the Main Menu button on the Navigation Bar.
2. Select the Implant button (Figure 21).

Figure 21: *Select the Implant button to create a patient chart*

3. Select the Patient View icon to access the Patient View screen.
4. The SQ-RX device model and serial numbers appear on the first line of the chart. The electrode model and serial numbers appear on the second line of the chart. The implant date appears on the third line of the chart (Figure 22). Using the on-screen keyboard, enter the following patient information:
   - Patient Name: up to 25 characters
   - Doctor Name: up to 25 characters
   - Doctor Info: up to 25 characters
   - Notes: up to 100 characters

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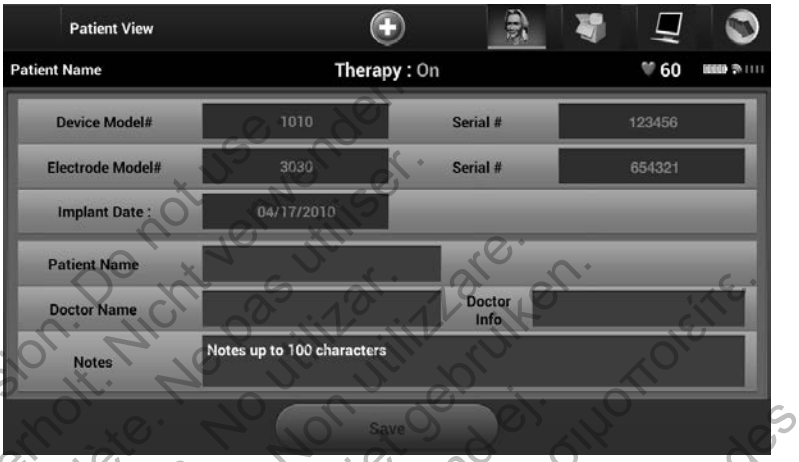

Figure 22: *Patient Chart screen*

Note: *The Notes field will automatically wrap the text with the presence of a space between any characters within the first line.*

5. Select the Save button to update the SQ-RX device with the patient information.

Note: *Failure to save the new patient information will result in loss of the entered data.*

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Automatic Setup

Before the SQ-RX device can be activated, it must go through an initial Automatic Setup Process at the time of the implant.

The Automatic Setup Process is initiated as follows:

1. Select the Main Menu button.
2. Select the Implant button.
3. Select the Auto Setup button on the Navigation Bar. The Automatic Setup screen appears (Figure 23).
4. Select Continue if the patient's heart rate is less than 130 bpm. For rates greater than 130 bpm, select the Cancel button and refer to the instructions for Manual Setup.

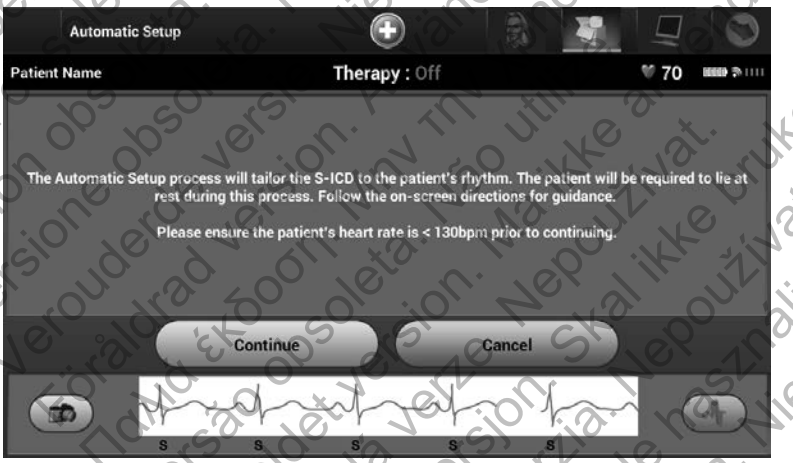
Automatic Setup
Patient Name
Therapy : Off
70
The Automatic Setup process will tailor the S-ICD to the patient's rhythm. The patient will be required to lie at rest during this process. Follow the on-screen directions for guidance.
Please ensure the patient's heart rate is < 130bpm prior to continuing.
Continue
Cancel
S
S
S
S
S

Figure 23: *Automatic Setup screen*

5. Once started the Automatic Setup will:
   - Perform the shock electrode integrity check to measure electrode impedance (Figure 24). Normal sub-threshold impedance range is < 400 Ohms.
   - Select the best sensing configuration. The sense electrode configuration appears on the printed report and can be viewed via the Manual Setup process.
   - Select the appropriate gain selection. The selected sense gain appears on the Printed Report and can be viewed via the Manual Setup process.

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Version überholt. Nicht verwenden.
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Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
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Föråldrad version. Använd ej.
Foreldet versjon. Skal ikke brukes.
Zastaralá verze. Nepoužívat.
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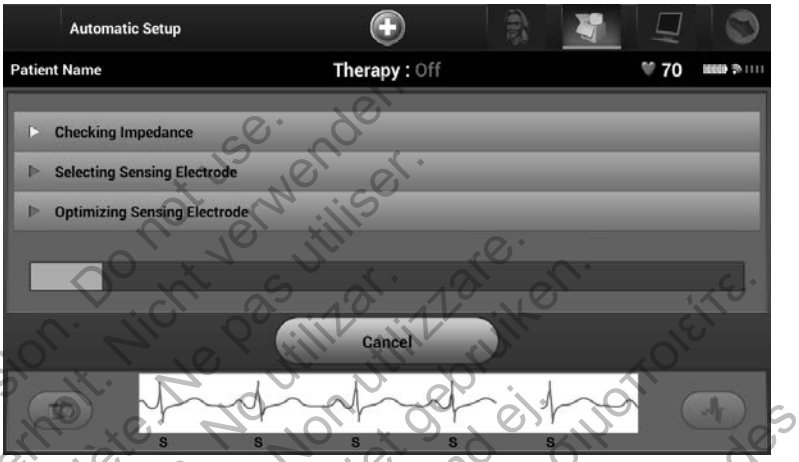

Figure 24: *Measuring electrode impedance*

The progress of the Automatic Setup process is shown in the status bar. When each function is complete, the arrow next to the function moves to a down position.

6. The Automatic Setup Sensing Optimization screen will be displayed. The programmer will display a message requesting that the patient sit up; however, this process can be omitted during the implantation procedure by selecting the Skip button (Figure 25).

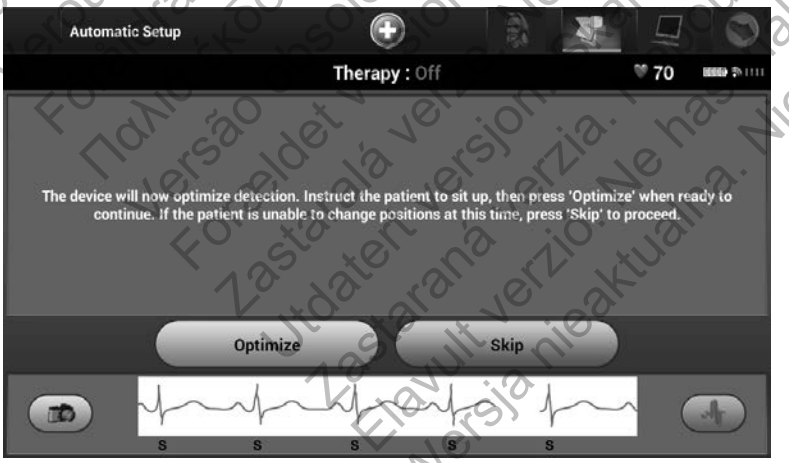
Automatic Setup
Therapy : Off
70
The device will now optimize detection. Instruct the patient to sit up, then press 'Optimize' when ready to continue. If the patient is unable to change positions at this time, press 'Skip' to proceed.
Optimize
Skip
S
S
S
S
S

Figure 25: *Automatic Setup screen*

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7. Select the Continue button to finish the Automatic Setup process. A confirmation screen will appear when Automatic Setup is complete (Figure 26).

Figure 26: *Confirmation of successful Automatic Setup*

8. Following the optional optimization process, the Acquire Reference S-ECG screen is displayed (Figure 27). Select the Continue button to acquire a reference S-ECG.

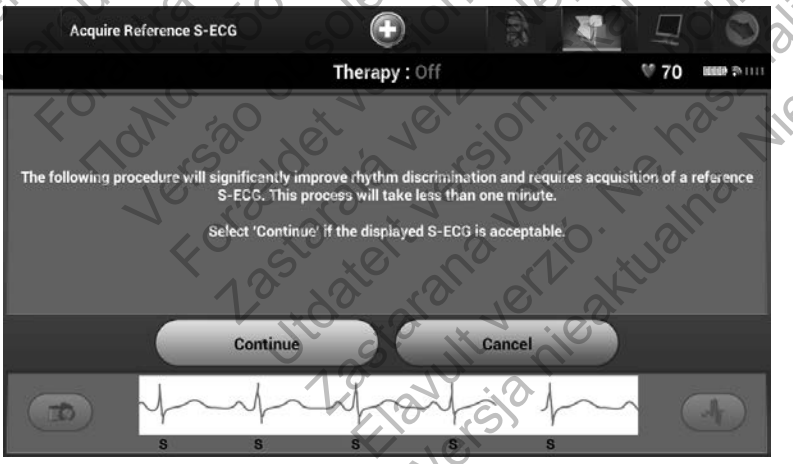

Figure 27: *Acquire Reference S-ECG screen*

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
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Versão obsoleta. Não utilize.
Foreldet versjon. Må ikke anvendes.
Zastaraná verzia. Nepoužívať.
Zastaralá verze. Nepoužívat.
Elavult verzió. Ne használja!
Utdatert versjon. Må ikke brukes.
Wersja nieaktualna. Nie używać.

9. Once the Reference S-ECG acquisition process begins, a status screen appears. The process may take up to one minute, during which the patient should remain still. During this process, a template of the patient's baseline QRS complex is stored in the SQ-RX device. Select Cancel at any time to end Reference S-ECG acquisition. When acquisition is complete, select the Continue button.

Programming Therapy Parameters

Once Automatic Setup has been completed, the SQ-RX device therapy parameters may be selected.

Note: *Data from clinical testing of the S-ICD System demonstrated a significant reduction in inappropriate therapy with the activation of the Conditional Shock Zone prior to hospital discharge.*

To set the therapy parameters:

1. Select the Main Menu button on the Navigation Bar.
2. Select the Implant button.
3. Select the Device Settings button on the Navigation Bar to display the Device Settings screen (Figure 28).

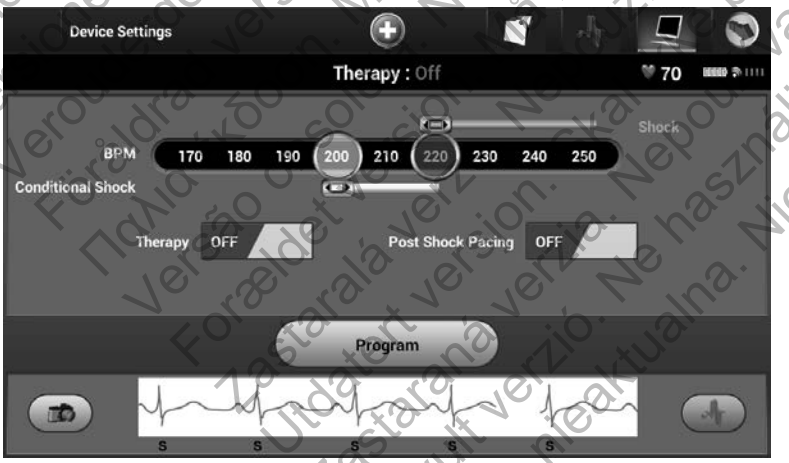

Figure 28: *Device Settings screen*

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
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Versão obsoleta. Não utilize.
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Zastaralá verze. Nepoužívat.
Updatert version. Skal ikke brukes.
Zastarana verzija. Nepotrebno.
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Wersja nieaktualna. Nie używać.

4. Select the On/Off Therapy switch to set the desired therapy mode (Figure 29).

Figure 29: *Setting the On/Off Therapy switch*

5. Select and drag the Conditional Shock Zone (yellow) and Shock Zone (red) slider bars to set the desired zone configuration.
   - The Shock Zone is programmable between 170 and 250 bpm in steps of 10 bpm.
   - The Conditional Shock Zone is programmable between 170 and 240 bpm in steps of 10 bpm. Enhanced detection criteria are automatically enabled when the Conditional Shock Zone is programmed.
   - When programming both the Shock Zone and Conditional Shock Zone, maintain at least a 10 bpm difference between the two zones. If the Conditional Shock Zone slider (yellow) is dragged over the Shock Zone slider (red), the two sliders will merge to create a single Shock Zone.
6. If post-shock pacing is desired, slide the Post Shock Pacing switch to the On position. (Post-shock bradycardia pacing occurs at a non-programmable rate of 50 bpm for up to 30 seconds. Pacing is inhibited if the intrinsic rate is greater than 50 bpm.)
7. Select the Program button to apply the changes and program the SQ-RX device. A screen will appear to confirm that the SQ-RX device settings were programmed (Figure 30). If the SQ-RX device does not accept the SQ-RX device programming, a Program Device alert screen will appear. Select the Try Again button to return to the Device Settings screen.

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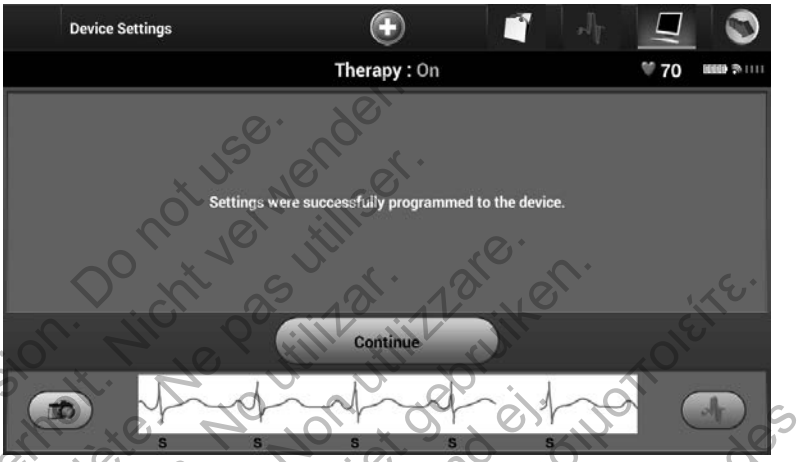

Figure 30: *Confirmation of programming*

8. Once programming is confirmed, select the Continue button to proceed to the next operation.

Note: *If any of the SQ-RX device settings are changed from the Device Settings screen and not subsequently programmed, the Pending Program Changes screen will appear. You may select Cancel to return to the Device Settings screen or select Continue to cancel all SQ-RX device setting changes.*

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Versão obsoleta. Não utilize.
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Zastaraná verzia. Nepoužívať.
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Wersja nieaktualna. Nie używać.

Defibrillation Testing

Once the SQ-RX device is implanted and Automatic Therapy is programmed On, defibrillation testing may be conducted.

Note: *Defibrillation testing is recommended at implant to confirm the ability of the S-ICD System to sense and convert VF.*

Note: *Episode data associated with rescue shocks, manual shocks, and induction testing is not stored in the SQ-RX device.*

To induce VF and test the S-ICD System:

1. Select the Programmer Main Menu button on the Navigation Bar to access the Main Menu.
2. Select the Patient Test button to setup the induction test (Figure 31).

Figure 31: *Select the Patient Test Button to access the Induction Test screen.*

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
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Versão obsoleta. Não usar.
Forældet version. Må ikke anvendes.
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Utdatert versjon. Skal ikke brukes.
Zastarana verzija. Nepoužívati.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

3. Select either standard (STD) or reverse (REV) polarity (Figure 32).
4. Select and drag the red marker to set the desired shock energy for the first delivered shock. The shock energy may be programmed from 10 to 80 J. A 15 J safety margin is recommended for defibrillation testing.

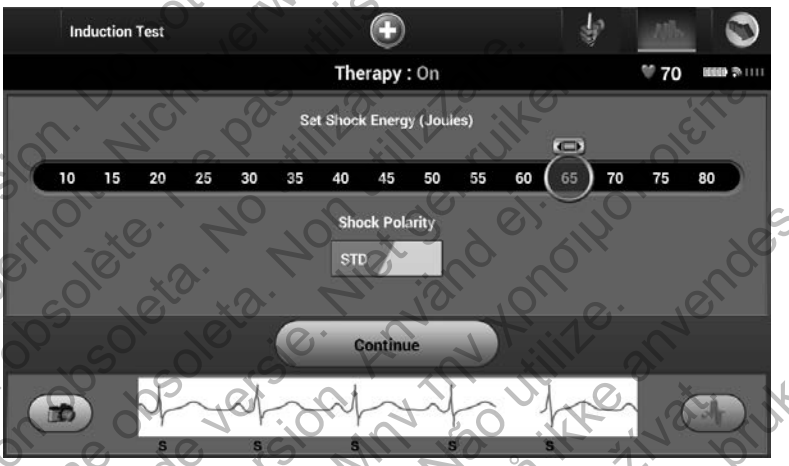

Figure 32: *Setting the desired first shock energy for defibrillation testing*

5. Select the Continue button to display the next Induction Test screen.

Note: *Ensure that noise markers ("N") are not present on the S-ECG prior to induction. The presence of noise markers may delay detection and therapy delivery.*

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
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Foreldet versjon. Må ikke anvendes.
Versão obsoleta. Não utilize.
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Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

6. Select and hold the Hold To Induce button for the desired duration (Figure 33).

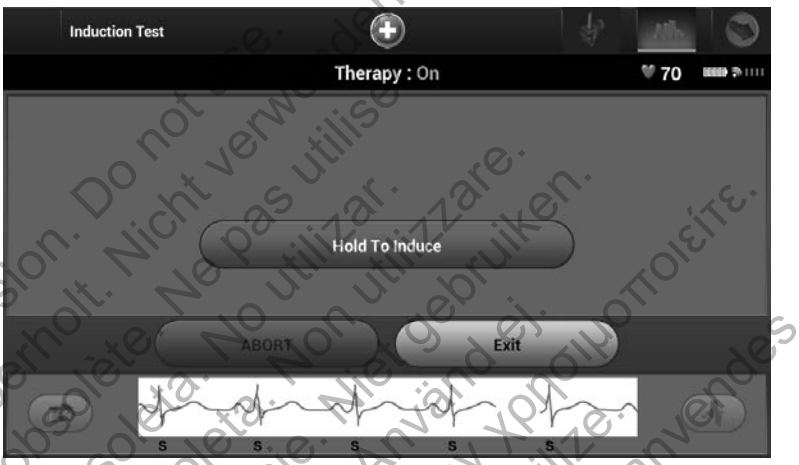

Figure 33: *Induction Test screen*

The following functions occur during the test:

- The S-ICD System induces ventricular fibrillation using 200 mA alternating current (AC) at 50 Hz. Induction continues until the Hold To Induce button is released (up to a maximum of 10 seconds per attempt).
- Arrhythmia detection and the Live S-ECG are suspended during AC induction. Once the Induction button is released, the programmer displays the patient's rhythm.
- Upon detection and confirmation of an induced arrhythmia, the S-ICD System automatically delivers a shock at the programmed energy output and polarity.
- If the shock fails to convert the arrhythmia, re-detection occurs and subsequent shocks are delivered at the SQ-RX device's maximum energy output (80 J).

Note: *Following the release of the Hold To Induce button, evaluate the sensing markers during the induced rhythm. The S-ICD System uses a lengthened rhythm detection period. Consistent tachy "T" markers indicate that tachyarrhythmia detection is occurring, and that capacitor charging is imminent. If a high degree of amplitude variation is noted during the arrhythmia, a slight delay may be expected prior to capacitor charging or shock delivery.*

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Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versione obsoleta. Non utilizzare.
Versión obsoleta. No utilizar.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Foreldet versjon. Må ikke anvendes.
Vanhentunut versio. Ei käytössä.
Zastaralá verze. Nepoužívat.
Elavult verzió. Ne használja.
Застаріла версія. Не використовувати.
Wersja nieaktualna. Nie używać.
Έκδοση που έχει καταργηθεί. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Foreldet versjon. Må ikke brukes.
Zastaralá verze. Nepoužívat.
Ukončená verzia. Nepoužívať.
Застарела версия. Не използвайте.

Note: *The SQ-RX device can deliver a maximum of five shocks per episode. At any time, an 80 J rescue shock can be delivered by pressing the Rescue Shock button.*

7. At any time prior to therapy delivery, the programmed energy may be aborted by selecting the red Abort button.
8. Select the Exit button to exit the induction process and return to the Main Menu screen.

Performing an SQ-RX Follow-up

Sensing Configuration and Automatic Setup

It is not necessary to perform Automatic Setup at each follow-up. If Automatic Setup is performed, resulting in a vector change, sensing should be reevaluated. After the setup process is complete, evaluate the streaming S-ECG during a pectoral exercise. Sensing performance during high rate exercises can also be performed. Acceptable sensing will yield "S" markers synchronous to all QRS complexes. If other markers are noted, use the Manual Setup process to evaluate other sensing configurations.

Note: *If Manual Setup was previously used to override a sensing configuration, careful consideration should be taken when selecting Automatic Setup.*

If an update to the reference S-ECG is desired due to a change in the patient's resting ECG, follow the Acquire Reference S-ECG instructions.

Viewing SQ-RX Device Status

Once communication is established, the programmer displays the Device Status screen with information regarding the current episodes and battery status of the SQ-RX device.

Outdated version. Do not use.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
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Vanhentunut versio. Älä käytä.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Foråldet version. Må ikke anvendes.
Zastaraná verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

To view this information:

1. Select the Main Menu button.
2. Select the Follow Up button.
3. Select the Device Status button on the Navigation Bar.
4. The Device Status screen will appear showing an overview of all SQ-RX device activity since the last communication session (Figure 34).

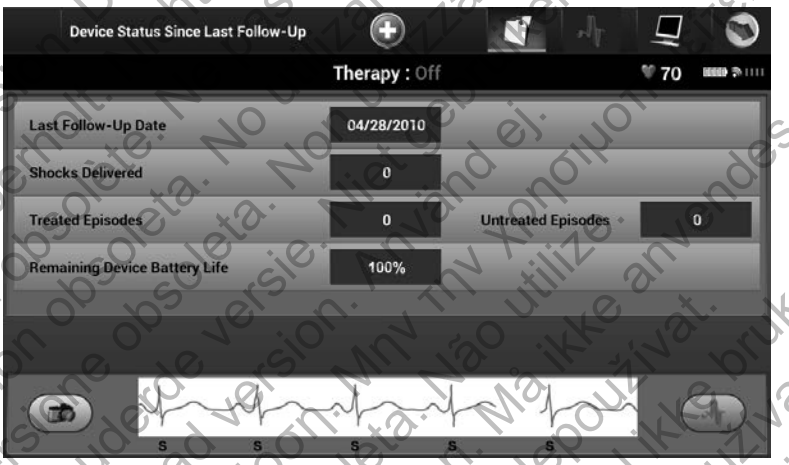

Figure 34: *Device Status screen*

The Device Status overview reports:

- Date of the last follow-up session
- Total number of shocks delivered since the last follow-up session
- Total number of treated episodes since the last follow-up session
- Total number of untreated episodes since the last follow-up session
- Remaining SQ-RX device battery life

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non usare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Foraldet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastarana verzija. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Viewing Stored Episodes

The SQ-RX device stores up to 25 treated and 20 untreated tachycardia episodes, which can be viewed during a patient's follow-up session. When the maximum number of episodes is exceeded, the most recent episode replaces the oldest stored episode; however, the first treated episode will not be overwritten.

Note: *If a spontaneous episode occurs during a patient's follow-up session while the SQ-RX device is wirelessly communicating with the programmer, the episode will not be stored.*

To view stored episodes:

1. Select the Main Menu button.
2. Select the Follow Up button.
3. Select the Captured and Stored Episodes S-ECG icon from the Navigation Bar.
4. Select the Episodes option to access the episodes pick list.
5. Select an episode (treated or untreated) from the list (Figure 35). The selected episode will be downloaded from the SQ-RX device and displayed.

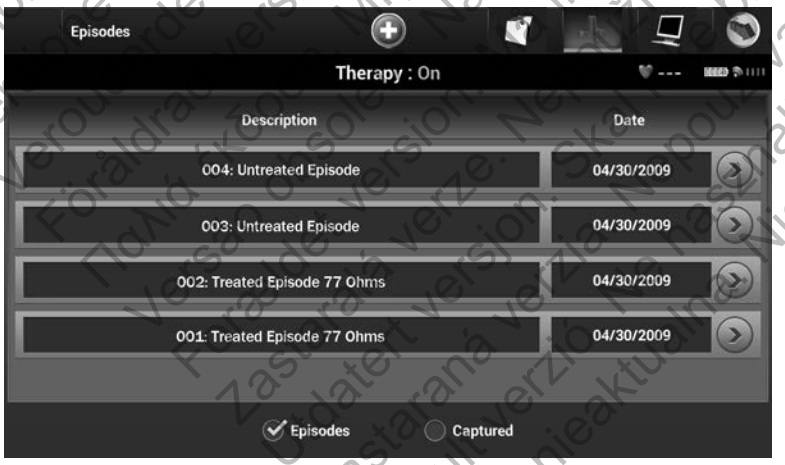

Figure 35: *Stored Episodes screen (scrollable list)*

Outdated version. Do not use!
Version überholt. Nicht verwenden!
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Foreldet versjon. Skal ikke benyttes.
Zastaralá verze. Nepoužívat.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

6. Each selected Episode screen also displays the programmed parameters and the stored S-ECG data at the time of episode declaration.
7. Select the Continue button to return to the Episodes pick list screen.

The following details are available for each episode:

Treated Episodes

Up to 128 seconds of S-ECG data is stored for each Treated Episode:

- **Pre-episode S-ECG:** Up to 44 seconds
- **First shock:** Up to 24 seconds of pre-shock S-ECG and up to 12 seconds of post-shock S-ECG
- **Subsequent shocks:** 6 seconds of pre-shock and 6 seconds post-shock S-ECG

Untreated Episodes

An Untreated Episode is defined as any high-rate episode that spontaneously terminates during the charging process, before a shock is delivered.

Up to 128 seconds of S-ECG data is stored for each Untreated Episode:

- **Pre-episode S-ECG:** 44 seconds of pre-episode S-ECG
- **Episode S-ECG:** Up to 84 seconds of tachycardia S-ECG data

Printing Reports from the Programmer

Printing Reports

Patient reports can be printed before or after a patient session is ended. It is recommended that a final report be printed immediately following the implant procedure. There are three patient reports:

- Summary Report
- Captured S-ECG Report
- Episode Reports

To print patient reports from either an Online or Offline session:

1. Select the Main Menu button to display the Main Menu screen.
2. Select the Print Reports button.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην τη χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Foráldalt verzió. Ne használja!
Zastaraná verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

3. Select the desired report type. A checkmark will appear next to the selected report. Report types are described below.
4. Select the Print button to print the selected reports.
5. Select the Cancel button to return to the previously accessed screen.

Summary Report

The Summary Report includes the following information:

- Patient Name
- Date of Current Follow-Up
- Date of Last Follow-Up
- Printed Report Date
- SQ-RX Device Model/Serial Number
- Electrode Model/Serial Number
- Implant Date
- Therapy Parameters
- Programmed Gain Settings and Sensing Configuration
- Initial Shock Polarity Configuration
- Episode Summary: Since Last Follow-Up and Since Initial Implant
- Battery Status
- Electrode Impedance Measurement
- SQ-RX Device Integrity Check, if applicable
- Programmer Software Version
- SQ-RX Device Software Version

To print a summary report, select the Summary Report button on the Print Reports screen.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolete. Ne pas utiliser.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλαιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Foráldult version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Captured S-ECG Report

To print a Captured S-ECG report:

1. Select the Captured S-ECG Report button from the Print Reports pick list screen. A list of the captured S-ECG strips is displayed. Select the button next to the Captured S-ECG(s) to be printed. A checkmark appears next to the selected Captured S-ECG (Figure 36).

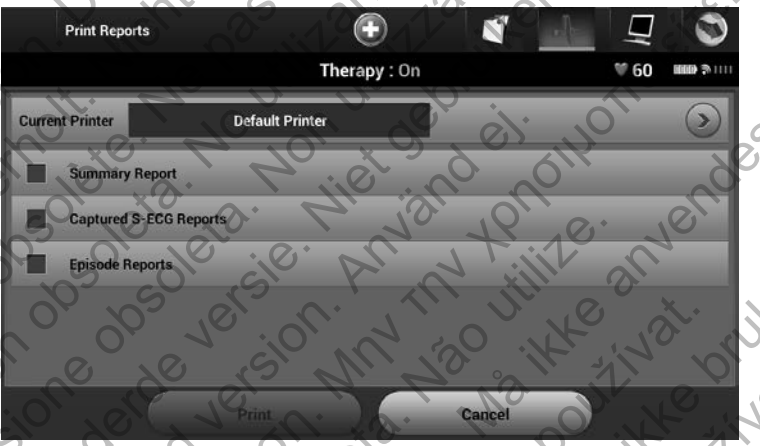

Figure 36: *Selecting Captured S-ECG Reports for printing*

2. Select Continue to return to the Print Reports pick list screen.
3. Select the Print button to print the selected report.
4. Select the Cancel button to return to the previously accessed screen.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non usare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verzia. Nepoužívať.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Episodes Report

To print an Episode Report:

1. Select the Episodes Report button on the Print Reports pick list screen. The Episode List screen appears showing a list of the stored episodes (Figure 37). Select the button next to the episode(s) to be printed. A checkmark appears next to the selected episode(s).

Figure 37: *Stored Episode List screen (scrollable).*

2. Select Continue to return to the Print Reports pick list screen.
3. Select the Print button to print the selected report.
4. Select the Cancel button to return to the previously accessed screen.

Note: *In order to be available for printing, episodes must be individually downloaded from the Stored Episodes Screen (Figure 35).*

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastarana verzija. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

S-ECG Features

The programmer provides the capability to view, adjust and capture the streaming S-ECG from the SQ-RX device.

S-ECG Rhythm Strip Markers

The system provides annotations to identify specific events on the S-ECG. These markers are shown in the S-ECG Markers on Programmer Display Screens and Printed Reports table (Table 2)and an example is shown in the Sample ECG Markers illustration (Figure 38).

Table 2: *S-ECG Markers on Programmer Display Screens and Printed Reports*

Description	Marker
Charging*	C
Sensed Beat	S
Noisy Beat	N
Paced Beat	P
Tachy Detection	T
Discard Beat	·
Shock	
Return to NSR*	

* Marker present on printed report but not on programmer display screen.

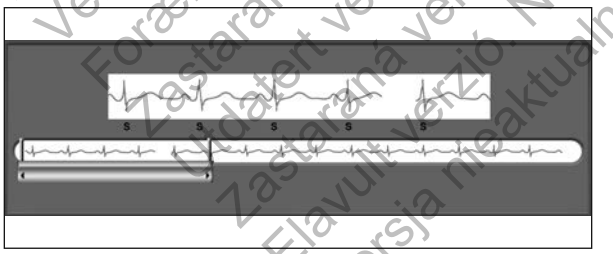

Figure 38: *Sample ECG markers*

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Udateret version. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

S-ECG Scale Settings

To adjust the real-time S-ECG amplitude and display speed scale settings:

1. Select the S-ECG Display Settings icon located to the right of the Live S-ECG window. The S-ECG Settings screen is displayed.
2. Select and drag the Gain or Sweep Speed Scale bars as desired (Figure 39). The S-ECG scale will change according to the selected setting. The gain setting controls the visual gain. The programmer defaults to Full Range for SQ-RX devices with a gain setting of x1 and to 1/2 Range for SQ-RX devices with a gain setting of x2. The Sweep Speed slider controls the display speed of the scrolling Live S-ECG. The nominal sweep speed setting is 25 mm/sec.

Figure 39: *Adjusting Gain and Sweep Speed*

Note: *Amplitude settings and display speed adjustments on scrolling real-time S-ECG and Captured S-ECGs affect the display screen settings only and have no impact on the SQ-RX device settings for sensing.*

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μη χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Forældet version. Skal ikke bruges.
Utdatert versjon. Skal ikke brukes.
Zastaraná verze. Nepoužívat.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Capture and View S-ECG Strips

The programmer can display, capture and store real-time S-ECG rhythm strips. The programmer saves a maximum of fifteen, 12-second, Captured S-ECG recordings comprised of:

- 8.5 seconds before activation of the Capture S-ECG button
- 3.5 seconds after activation of the Capture S-ECG button

If an additional recording is required, then the oldest previous recording is replaced with the new recording.

To capture a new S-ECG rhythm strip:

1. Select the Capture S-ECG button located to the left of the Live S-ECG window (Figure 40). The S-ECG will scroll across the display screen. Calipers appear below the Captured S-ECG rhythm strip (Figure 41). Each 12-second recording is date and time stamped according to the programmer's date and time setting.

Figure 40: *Select the Capture S-ECG button*

Figure 41: *Captured S-ECG rhythm strip*

Outdated version. Do not use!
Version überholt. Nicht verwenden!
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Forældet version. Må ikke anvendes.
Föråldrad version. Använd inte.
Πολύ παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Foreldet versjon. Skal ikke brukes.
Zastarała wersja. Nie używać.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Utdatert versjon. Skal ikke brukes.
Wersja nieaktualna. Nie używać.

2. Select and move the calipers across the S-ECG strip to measure intervals as desired.
3. Select the Continue button to return to the previously accessed screen.

To view a previously Captured S-ECG:

1. Select the Main Menu button.
2. Select the Follow Up button.
3. Select the Captured and Stored Episode S-ECG button. The Captured S-ECG pick list screen appears.
4. Select one Captured S-ECG from the list. The Captured S-ECG Details screen appears.
5. Select and drag the calipers to view details.
6. Select the Continue button to return to the Captured S-ECG list screen.

Utilities Menu

The programmer Utilities menu provides access to additional SQ-RX device features. These include Acquire Reference S-ECG, Beeper Control, Manual Setup and Smart Charge.

To access the Utilities menu during an Online session:

1. Select the Main Menu button to display the Main Menu screen.
2. Select the Utilities button. The Utilities screen appears (Figure 42).

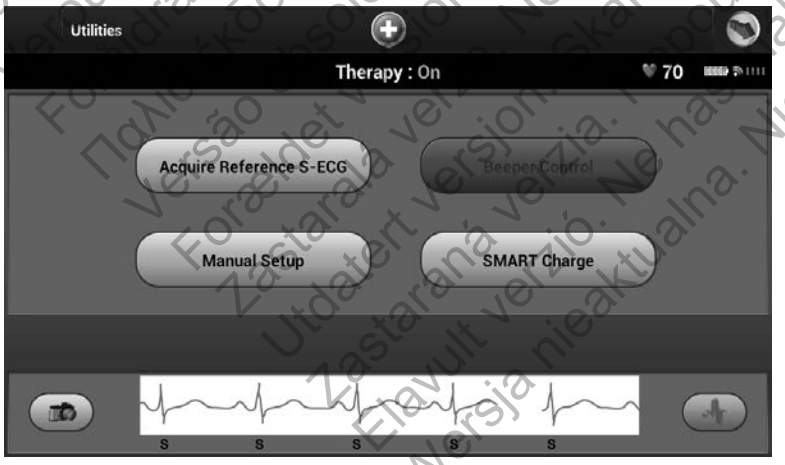

Figure 42: *Utilities screen*

Outdated version. Do not use.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Forældet version. Må ikke anvendes.
Utdatert versjon. Må ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Acquire Reference S-ECG

To acquire a manual Reference S-ECG:

1. Select the Acquire Reference S-ECG button on the Utilities menu to access the Acquire Reference S-ECG screen.
2. Select Continue to acquire a Reference S-ECG. The programmer will begin acquiring the Reference S-ECG. A message will appear requesting that the patient remain still (Figure 43). The reference S-ECG QRS template is recorded and stored in the SQ-RX device.
3. Select the Continue button to complete the process and return to the Utilities screen. The Cancel button can be used at any time to end S-ECG acquisition and return to the Utilities screen.

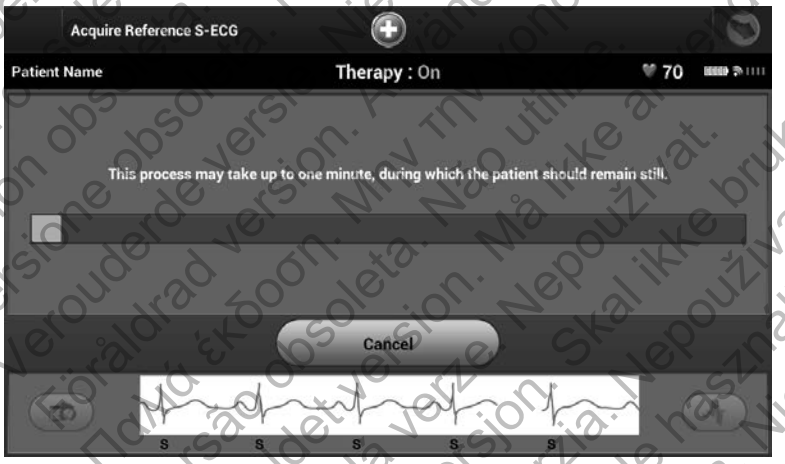
Acquire Reference S-ECG
Patient Name
Therapy : On
70
This process may take up to one minute, during which the patient should remain still.
Cancel

Figure 43: *The patient should remain still while the Reference S-ECG is acquired*

Beeper Control

The SQ-RX device has an internal alert system that emits an audible beeping tone when an alert condition occurs. Alert conditions may include Elective Replacement Indicator (ERI), End of Life (EOL), electrode impedance out of range, prolonged charge times, failed Device Integrity Check and irregular battery depletion. Beeper Control allows activation or suppression of the beeper.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην τη χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Foreldet versjon. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Once an alert condition is triggered, audible tones beep for 16 seconds every nine hours until the alert condition is resolved. Beeper Control is automatically enabled when the SQ-RX device is taken out of Shelf mode.

To reset the Beeper Control:

Note: *The Beeper Control display screen is enabled only when an alert condition occurs. If an alert condition is activated, a notification screen will appear upon connection.*

1. Select the Main Menu button to display the Main Menu.
2. Select the Utilities button to display the Utilities Menu.
3. Select the Beeper Control button.
4. Select the Reset Beeper button to suspend audible beeping tones triggered by an alert condition (Figure 44). If the alert condition is not corrected, the audible beeping tones will be reactivated during the next automatic S-ICD System self-check.

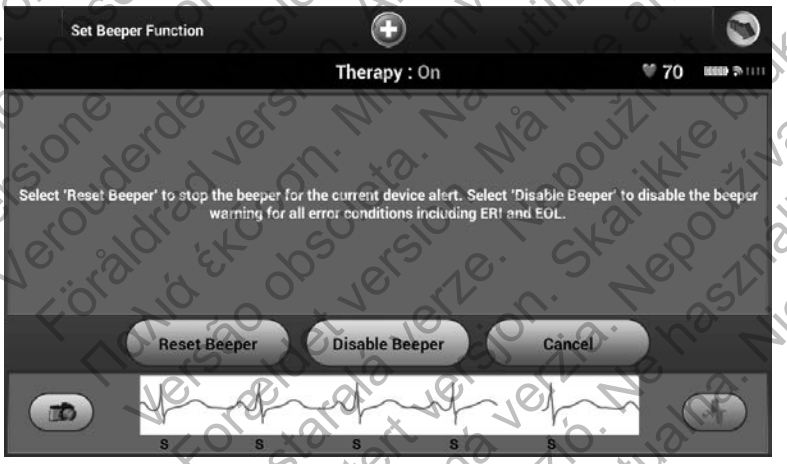

Figure 44: *Resetting the Beeper*

5. The disable Beeper feature is enabled when ERI is reached or EOL occurs. If desired, select disable Beeper when ERI or EOL occurs. Beeper tones are permanently disabled.

   Note: *If beeper is disabled alert conditions will not trigger audible tones.*

Outdated version. Do not use.
Version ungültig. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μη χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastarała wersja. Nie używać.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Manual Setup

Manual Setup enables the user to perform the electrode integrity test and select the electrode sensing configuration and gain setting in the SQ-RX device.

1. From the Utilities Menu, select the Manual Setup button. The Impedance Test screen appears (Figure 45).
2. Select the Test button to perform the electrode integrity test.

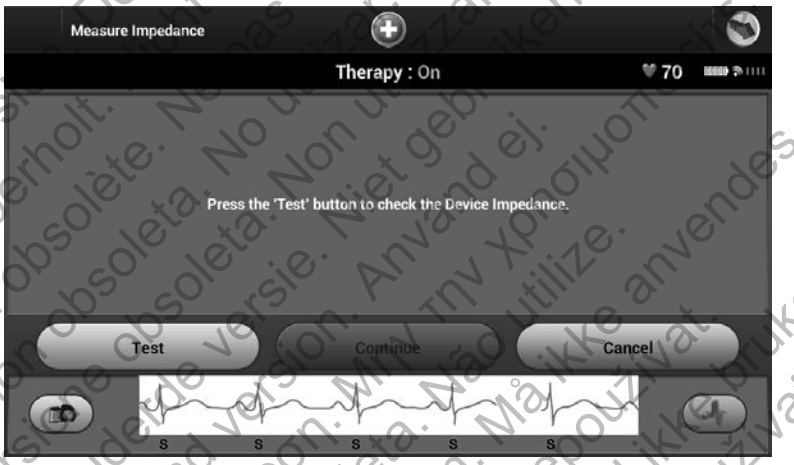

Figure 45: *Impedance test screen*

3. Select Continue to proceed or select Test to retry. The sensing configuration can be evaluated by temporarily activating any of the vectors or gain settings. The Live S-ECG and markers will reflect the temporary selections for evaluation purposes.
4. There are three available sensing vectors that can be manually selected:
   - **Primary:** Sensing from the proximal electrode ring on the subcutaneous electrode to the surface of the active SQ-RX device
   - **Secondary:** Sensing from the distal sensing electrode ring on the subcutaneous electrode to the surface of the active SQ-RX device
   - **Alternate:** Sensing from the distal sensing electrode ring to the proximal sensing electrode ring on the subcutaneous electrode

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Versão obsoleta. Não utilize.
Foreldet versjon. Må ikke anvendes.
Zastaraná verzia. Nepoužívať.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

The gain setting adjusts the sensed S-ECG signal sensitivity. It may be manually selected via the Select Gain slider switch (Figure 46).

Figure 46: *Gain adjustment*

- 1x Gain (± 4 mV): 1x Gain should be selected when the signal amplitude is large enough to cause clipping when the 2x gain is selected.
- 2x Gain (± 2 mV): 2x Gain should be selected when the signal amplitude is small enough to allow use of a more sensitive setting without causing clipping of the captured signal. The 2x gain selection amplifies the signal twice as much as the 1x gain selection.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

To program the manually selected sense configuration:

1. Select the Program button to save the sense vector and gain settings.
2. The Acquire Reference S-ECG process is automatically enabled during the Manual Setup Process. Select the Continue button to acquire a reference S-ECG. A confirmation screen will appear when the captured reference S-ECG is acquired (Figure 47).
3. Select the Continue button.

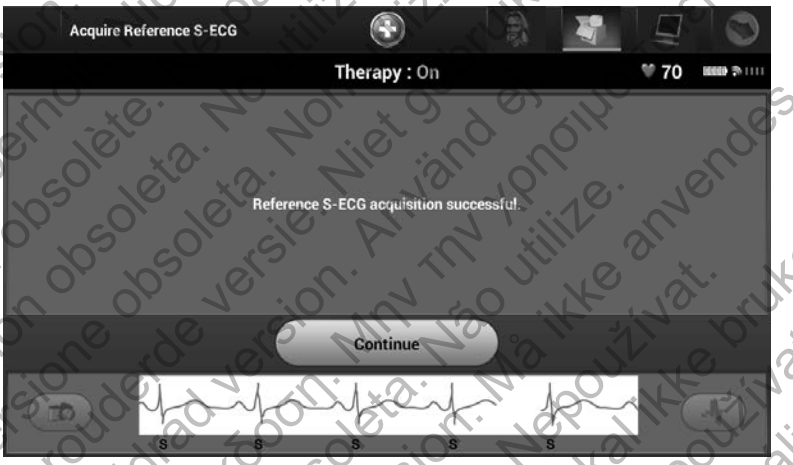

Figure 47: *Captured Reference S-ECG confirmation*

Smart Charge

Through the Smart Charge feature, the SQ-RX device charge initiation sequence adapts to the occurrence of non-sustained ventricular arrhythmia episodes by delaying capacitor charging. This conserves battery longevity and may prevent unnecessary shocks for non-sustained arrhythmias.

Smart Charge is enabled automatically when an untreated ventricular arrhythmia episode is recorded. To reset the Smart Charge feature:

1. Select the Main Menu button.
2. Select the Utilities button on the Main Menu to display the Utilities Menu.
3. Select the Smart Charge button. The Reset Smart Charge screen appears (Figure 48).

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Foreldet versjon. Må ikke anvendes.
Versão obsoleta. Não utilize.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Figure 48: *Reset Smart Charge screen*

4. Select the Reset button to reset the Smart Charge to zero or press Cancel to return to the Utilities Menu without resetting the Smart Charge.
5. A confirmation window will appear with the message: "Smart Charge successfully reset."
6. Press the Continue button to return to the Utilities screen.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Additional Programmer Functions

Rescue Shock

The Rescue Shock button is available on the programmer display when the SQ-RX device Setup Process is complete and an SQ-RX device is actively communicating with the programmer. During active communication, a maximum (80 J) rescue shock can be delivered upon programmer command.

To deliver a rescue shock:

1. Select the red Rescue Button at the top of the programmer screen. The Rescue Shock screen appears (Figure 49).

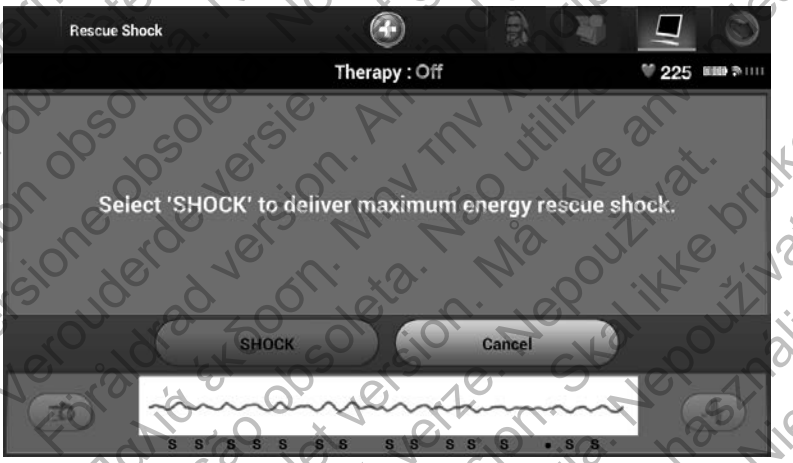

Figure 49: *Rescue Shock screen*

2. Select the Shock button to begin charging the SQ-RX device for a Rescue shock. A red background screen with the word "Charging" will appear (Figure 50). Selecting the Abort button will prevent delivery of a rescue shock and will return to the Device Settings screen.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Πολύ άκυρη. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Foreldet versjon. Må ikke anvendes.
Zastaraná verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaralá verze. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Figure 50: *Abort Rescue Shock*

3. A confirmation screen will appear with notification that the shock was delivered successfully along with the corresponding shock impedance (Figure 51).

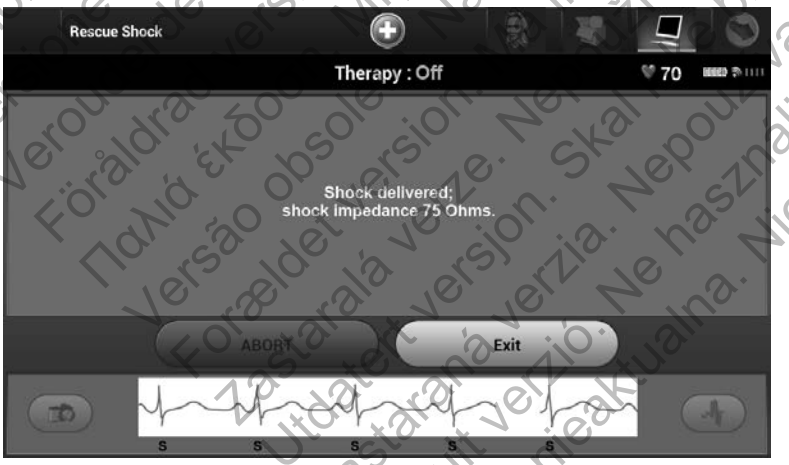

Figure 51: *Confirmation of Rescue Shock delivery*

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

If for any reason the shock could not be delivered, a red background screen will appear with a message stating "The Shock could not be delivered."

Note: *In the event telemetry is lost, SQ-RX device commands, including Rescue Shocks, will not be available until telemetry is reestablished.*

Manual shock

Manual Shock allows the user to deliver a synchronized shock during a sinus rhythm, an atrial rhythm or a ventricular rhythm. The shock energy level is user-configured in the 10 to 80 joule range (Figure 52). Manual shock may also be utilized at a low energy to assess system impedance/integrity either at implant or as warranted by patient condition. A manual shock may be administered with the S-ICD detection zone(s) either ON or OFF.

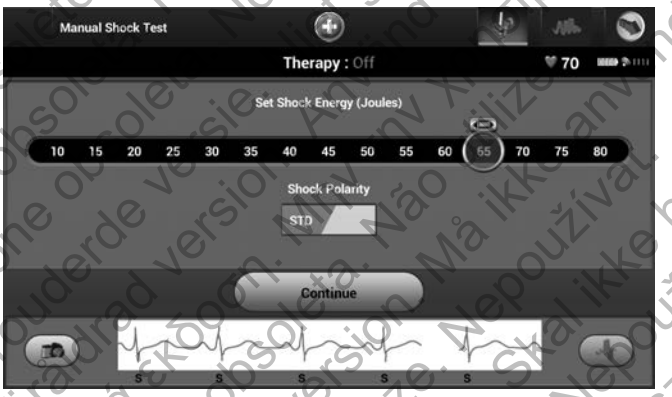

Figure 52: *Manual shock*

S-ICD System Magnet Model 4520

Model 4520 Magnet (the "magnet") is a nonsterile accessory used to inhibit the delivery of therapy from the SQ-RX device. Apply the magnet flat against the skin directly over the implanted SQ-RX device for a minimum of one (1) second to suspend arrhythmia detection. Removal of the magnet will return the SQ-RX device to normal operation. If the magnet is applied during an episode, the episode will not be stored in the SQ-RX device memory.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Forældet version. Må ikke anvendes.
Vanhentunut versio. Ei saa käyttää.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Other behaviors of magnet application:

- Inhibit shock therapy delivery
- Terminate post-shock pacing therapy
- Prohibit arrhythmia induction testing
- Activate the SQ-RX device's beeper with each detected QRS complex for 60 seconds

Note: *A programmer commanded Rescue Shock can override the use of the magnet as long as the magnet was in place prior to the initiation of the programming command. If the magnet is applied after the initial command, the Rescue Shock will be terminated.*

Note: *Magnet application does not affect wireless communication between the SQ-RX device and the programmer.*

Charging the Programmer

When not in use, it is recommended that the programmer remain connected to the external power supply. This will ensure that the internal battery is adequately charged.

Cleaning the Programmer

Keep the programmer away from dust and dirt. Do not use harsh chemicals, cleaning solvents, or strong detergents to clean the programmer and wand.

To clean the programmer and wand as needed:

1. Turn the Programmer Off.
2. Gently wipe the programmer screen with a soft, clean, dry cloth.
3. Clean the programmer plastic case and the wand by wiping them with an isopropyl alcohol-moistened cloth.
4. Dry the programmer immediately to remove residue.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Versão obsoleta. Não utilize.
Föråldrad version. Använd ej.
Verouderde versie. Niet gebruiken.
Εσφαλμένη έκδοση. Μην την χρησιμοποιείτε.
Πδλλά επδοπη. Μην χρησιμοποιείτε.
Foreldet versjon. Må ikke anvendes.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaraná verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Service

There are no user-accessible or user-serviceable parts or components in the programmer. If any service, repair, or replacement of internal components is needed, the programmer must be returned to Cameron Health/Boston Scientific. Contact your Cameron Health/Boston Scientific Representative or the customer service department for instructions and return packaging.

When requesting service, please provide information concerning the nature of the failure and the manner in which the equipment was used when the failure occurred. The model number and serial number should also be provided. Before returning any products to the factory, call Cameron Health/Boston Scientific customer service or your local representative for a Return Authorization number.

Maintenance Check

Prior to each use, you should perform a visual inspection and verify the following:

- Mechanical and functional integrity of the programmer, cables, and accessories.
- Legibility and adherence of the programmer labels.
- Startup screen appears a few seconds after you turn on the programmer. (The normal power-up process verifies that the programmer has passed its internal checks and is ready for use.)

Safety Measurements

National regulations may require that the user, manufacturer, or manufacturer representative periodically perform and document safety tests of the programmer. If such testing is required in your country, follow the testing interval and extent of testing as regulated in your country. If you do not know the national regulations in your country, please contact your Cameron Health/Boston Scientific representative. If IEC/EN 62353 is a required standard in your country, but no specific testing or interval is specified, it is recommended that you perform these safety tests using the direct method as specified in IEC/EN 62353 at an interval of every 24 months. Test values are shown in the Nominal Specifications table (Table 10).

Programmer End of Life

The programmer and accessories are designed to provide years of service under typical use. To dispose of, return, or exchange a programmer, contact your Cameron Health/Boston Scientific representative or the customer service department for instructions and return packaging. Do not dispose of the programmer in the trash or at electronics recycling facilities.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Version obsolète. Ne pas utiliser.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Foreldet versjon. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Zastarała wersja. Nie używać.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

TROUBLESHOOTING

This section presents potential programmer issues and the possible solutions. Of note, restarting the programmer can often resolve many of the issues listed below. The programmer can be restarted by pressing and holding the power button until the system shutdown menu appears and then choosing the "Restart" option.

Contact your Cameron Health/Boston Scientific representative or the customer service department for additional assistance.

Inability to Print

If unable to print, follow the steps below:

1. Ensure that the printer is turned On and that it contains paper and a sufficient ink supply.
2. Check printer feed for paper jam.
3. Ensure, as applicable, that the wireless function is enabled on the printer or that the Cameron Health/Boston Scientific approved wireless adapter is fully inserted into the left side of the printer.

No Printer Available

The No Printer Available screen will appear if a printer was not set up. Select the Try Again button or refer to the Printer Selection section for instructions.

Touch Screen Inactive while Connected to AC Power

If the touch screen does not function while the programmer is connected AC power via the external power supply, disconnect and reconnect the external power supply and restart the programmer.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaraná verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Loss of Communication with Printer

When communication between the programmer and the printer fails, a Printing Error screen will appear with a message stating "Error while printing reports. Press "Continue" to try printing any remaining reports, or "Cancel" to cancel the current print job."

If this occurs:

1. Select the Try Again button to reconnect to the printer.
2. Verify that the selected printer has, as applicable, the wireless function enabled or a Cameron Health-approved wireless adapter inserted in the left side of the printer.
3. Move the programmer closer to the printer.
4. Move any devices and the associated cables that may be interfering with the RF communication.

Inability to Communicate With the SQ-RX Device

If the programmer is unable to communicate with the SQ-RX device, follow the steps below:

1. Attempt to reposition the wand.
2. Select Scan For Devices from the Main Menu or select Scan Again from the Device List screen to locate the desired SQ-RX device.
3. Move any equipment and associated cables that may be interfering with RF communication.
4. If available, attempt to communicate using a different S-ICD System programmer and/or wand.
5. Apply a pulse generator magnet to the SQ-RX device to elicit beeper tones. Remove the magnet and re-attempt communication.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

COMPLIANCE STATEMENTS

Federal Communications Commission (FCC) US
This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 - 406.00 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

FCC ID SDYCHI2020

1999/5/EC (R&TTE Directive)
The S-ICD System contains radio equipment in the frequency range 402 MHz to 405 MHz for ultra low power active medical implants. Cameron Health hereby declares that this transmitter is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. To obtain a full-text Declaration of Conformity please contact Cameron Health/Boston Scientific using the information given on the inside front cover or back page of this manual.

EMI/RFI
This equipment has been tested and found to comply with the applicable limits for medical devices, IEC 60601-1-2:2007 or Active Implantable Medical Device Directive 90/385/EEC.

Although this testing shows the device to provide reasonable protection against harmful interference in a typical medical installation, there is no guarantee that interference will not occur in a particular installation. If the device does cause harmful interference the user is encouraged to try and correct the interference by the following measures:

- Reorient or relocate the device
- Increase the separation between the devices
- Connect the equipment to an outlet on a different circuit
- Contact your Cameron Health/Boston Scientific representative or customer service

Outdated version. Do not use.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Vanhentunut versio. Älä käytä.
Foreldet versjon. Skal ikke brukes.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Zastarané verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Table 3: Declaration Electromagnetic Emission

The Q-TECH Model 3200 programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Q-TECH Model 3200 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The Q-TECH Model 3200 programmer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Q-TECH Model 3200 programmer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Table 4: Declaration Electromagnetic Immunity Part 1

The Q-TECH Model 3200 programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Q-TECH Model 3200 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, then the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T 30% dip in U_T) or 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Q-TECH Model 3200 programmer requires continued operation during power mains interruptions, it is recommended that the Q-TECH Model 3200 programmer be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Outdated version. Do not use.
Version obsolète. Ne pas utiliser.
Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Versão obsoleta. Não utilize.
Föråldrad version. Använd ej.
Foreldet versjon. Må ikke anvendes.
Vanhentunut versio. Ei käytössä.
Zastaralá verze. Nepoužívejte.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívajte.
Elavult verzió. Ne használja.
Wersja nieaktualna. Nie używać.

Table 5: Declaration Electromagnetic Immunity Part 2

The Q-TECH Model 3200 programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Q-TECH Model 3200 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Q-TECH Model 3200 programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 KHz to 80 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Q-TECH Model 3200 is used exceeds the applicable RF compliance level above, the Q-TECH Model 3200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Q-TECH Model 3200.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

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Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Foreldet versjon. Må ikke brukes.
Vanhentunut versio. Ei saa käyttää.
Zastaralá verze. Nepoužívat.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Table 6: Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Q-TECH Model 3200 programmer

The Q-TECH Model 3200 programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Q-TECH Model 3200 programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Q-TECH Model 3200 programmer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 7: EMI/RFI Information

Wireless Connection From Programmer	Frequency	Bandwidth	FCC Designation	R&TTE Class
Programmer Wireless Adapter and Device	403.5 MHz	< 300 KHz	CFR 47, Part 951, MICS	Class 1 Subclass 47
Printer Adapter	2.400 - 2.4835 GHz	< 1000 KHz Maximum	CFR 47, Part 15, Class B	Class 2 Subclass 21

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Table 8: Product Guidelines

Component	Requirement	
DC Power		
Battery pack type	4000 mAh 3.7 volt lithium-ion battery pack	
Charge time	Approximately 5 hours	
Power Supply		
Input	100 – 240 VAC, 50 - 60 Hz, 0.5A	
Output	5.5 VDC, 3.64A Power: 20 W	
Manufacturer/Model	Elpac Power Systems MWA020005A	
Environment	**Operating**	**Storage**
Temperature	15° C to +38° C (+59° F to +100° F)	-10° C to +55° C (+14° F to +131° F)
Relative humidity	5% to 93% maximum at 40° C, non-condensing	5% to 93% maximum at 40° C, non-condensing
Atmospheric pressure	50 kPa to 106 kPa (7.252 psi to 15.374 psi)	50 kPa to 106 kPa (7.252 psi to 15.374 psi)

Table 9: Specifications

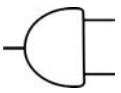
Component	Specification
Dimensions Width x Depth x Height	24.0 cm x 12.7 cm x 2.6 cm 9.4 in x 5.0 in x 1.0 in
Weight	.6 kg, 1.3 lbs
Standard Screen Display	WVGA, 1024 x 600 pixels, 16M TFT

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No usar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilizar.
Foreldet version. Må ikke brukes.
Utdatert versjon. Skal ikke brukes.
Zastaraná verze. Nepoužívat.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Table 10: Nominal Specifications	
Characteristic	**Nominal**
Electrical Safety Testing – IEC 60601-1:2005 / ANSI/AAMI ES60601-1:2005 allowed values	
Earth resistance	100 mΩ
Earth leakage current	5 mA Normal Condition (NC)
	10 mA Single Fault Condition (SFC)
Patient leakage current	100 µA Normal Condition (NC)
	500 µA Single Fault Condition (SFC) (mains on applied parts)
Electrical Safety Testing – IEC 62353:2008 allowed values	
Earthbond testing (Groundbond testing)	300 mΩ including power cable not exceeding 3 meters
Equipment leakage — direct method	500 µA
Patient leakage current — direct method (Wand, BF)	<= 5000 µA
Safety Features	
Defibrillator protection	to 5000 V, 400 J

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Table 11: Packaging Symbols: Q-TECH Programmer

Symbol	Specification	Symbol	Specification
	Type BF Applied Part Symbol – Indicates connection of Type BF applied part		**Manufacturer** – Name and address of the manufacturer
EC REP	**European Community Representative** – Authorized representative in the EU community		**Storage Temperature** – Product stored with temperature limitations
PART	**Part Number–** Component number		**Radio** – Non-ionizing electromagnetic radiation
	Do Not Dispose – Do not dispose of in trash		**Follow instructions for use**
SN	**Serial Number** – Serial number of the programmer		**Risk Of Shock** – Indicates the risk of electric shock
CE 0344 2013	**Conformité Européenne** – Product fully complies with European Directive AIMD 90/385/EEC		**Fragile: Handle with Care** – Transport and store with care
	Keep Dry – Ship and store in a dry place		**Date of Manufacture** – Date programmer was manufactured
	Electrostatic Discharge – Identifies a connector not tested for immunity to electrostatic discharge	REF	**Reference Number** – Catalog number
	**Power plug** – Storage location of power cord		**Door, open** – Open the flap

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην χρησιμοποιείτε.
Wersja obsoleta. Nie używać.
Zastaralá verze. Nepoužívat.
Foreldet versjon. Skal ikke brukes.
Zastarala verzija. Nepoužívať.
Elavult verzió. Ne használja.
Wersja nieaktualna. Nie używać.

Table 12: Packaging Symbols: Q-TECH Programmer Wand

Symbol	Specification	Symbol	Specification
LOT	**Lot number** – Batch code	NON STERILE	**Non-Sterile –** Used to indicate the product is not sterile

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Warranty

Cameron Health/Boston Scientific, Inc. offers a 2-year limited warranty on the Q-TECH Programmer to the user or using facility. Please contact your Cameron Health/Boston Scientific office or local representative for details. The warranty on the Q-TECH Programmer does not extend to any product that has been tampered with, altered, or repaired by any person other than an employee of Cameron Health/ Boston Scientific organization.

Outdated version. Do not use!
Version überholt. Nicht verwenden!
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

Outdated version. Do not use.
Version überholt. Nicht verwenden.
Version obsolète. Ne pas utiliser.
Versión obsoleta. No utilizar.
Versione obsoleta. Non utilizzare.
Verouderde versie. Niet gebruiken.
Föråldrad version. Använd ej.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Versão obsoleta. Não utilize.
Forældet version. Må ikke anvendes.
Zastaralá verze. Nepoužívat.
Utdatert versjon. Skal ikke brukes.
Zastaraná verzia. Nepoužívať.
Elavult verzió. Ne használja!
Wersja nieaktualna. Nie używać.

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EC REP

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